

## 2018 Current Fiscal Year Report: Advisory Commission on Childhood Vaccines

Report Run Date: 06/05/2019 07:44:32 AM

### 1. Department or Agency

Department of Health and Human Services

### 2. Fiscal Year

2018

### 3. Committee or Subcommittee

Advisory Commission on Childhood Vaccines

### 3b. GSA Committee No.

36

### 4. Is this New During Fiscal Year?

No

### 5. Current Charter

07/21/2018

### 6. Expected Renewal Date

07/21/2020

### 7. Expected Term Date

### 8a. Was Terminated During Fiscal Year?

No

### 8b. Specific Termination Authority

### 8c. Actual Term Date

### 9. Agency Recommendation for Next Fiscal Year

Continue

### 10a. Legislation Req to Terminate?

Not Applicable

### 10b. Legislation Pending?

Not Applicable

### 11. Establishment Authority

Statutory (Congress Created)

### 12. Specific Establishment Authority

42 U.S.C. 300aa-19

### 13. Effective Date

10/01/1988

### 14. Committee Type

Continuing

### 14c. Presidential?

No

### 15. Description of Committee

National Policy Issue Advisory Board

### 16a. Total Number of Reports

No Reports for this Fiscal Year

### 17a. Open Meetings and Dates 4 17b. Closed Meetings and Dates 0 17c. Partially Closed Meetings and Dates 0 17d. Total Meetings and Dates 4

Purpose

Start

End

The ACCV conducted its 104th quarterly meeting in Rockville, MD on December 8, 2017. The meeting began with updates from the Division of Injury Compensation (DICP) and the Department of Justice (DOJ). The ACCV then reviewed several petitions requesting that injuries be added to the Vaccine Injury Table (Table). The statute states: "Any person (including the ACCV) may petition the Secretary of the Department of Health and Human Services (HHS) to propose regulations to amend the vaccine injury table." The petition is referred to the ACCV for its recommendations. Then, the Secretary is required to either: 1) conduct a rulemaking on the matter proposed in the petition; or 2) publish in the Federal Register a statement of reasons for not conducting such proceedings. Even if an injury is not listed on the Table or the condition does not satisfy the Table's requirements, a claim may still be filed. The petitioner must show that the vaccine caused the injury and/or condition by a preponderance of the evidence (more likely than not). The Program compensates many non-Table injuries each year, typically through a negotiated settlement between the parties in which HHS has not concluded, based upon a review of the evidence, that the vaccine caused the alleged injury. The program received a second petition requesting that food allergies be added to the Table. Dr. Narayan Nair, Director, DICP, reminded the ACCV that the first petition was received in September 2015 and presented at the December 2015 ACCV meeting where they voted unanimously not to add food allergies to the Table. A March 29, 2016, Federal Register Notice stated the reasons food allergies were not added to the Table. Since that time, DICP conducted additional reviews of medical and scientific literature which still do not support adding this injury to the Table. The program also received petitions requesting that several other conditions be added as injuries to the Table. These included: 1) autism 2) asthma, 3) tics, 4) Pediatric Autoimmune and Neuropsychiatric Syndrome (PANS), Pediatric Infection-Triggered Autoimmune Neuropsychiatric Disorder (PITAND) and Pediatric Autoimmune Neuropsychiatric Disorder Associated with group A Streptococcus (PANDAS), and 5) Experimental Autoimmune Encephalomyelitis (EAE) and/or Acute Demyelinating Encephalomyelitis (ADEM). DICP Medical Officers presented reviews of medical and scientific literature regarding vaccines and these conditions. After discussions, the ACCV did not recommend that any of these conditions be added as injuries to the Table. The next step is for the Secretary to publish a Federal Register notice explaining why these injuries will not be added to the Table. The day ended with program updates from the Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease (NIH), the Center for Biologics, Evaluation, and Research (FDA), and the National Vaccine Program Office (NVPO).

12/08/2017 - 12/08/2017

The ACCV conducted its 105th quarterly meeting by teleconference and Adobe connect on March 8, 2018. The morning began with the nomination and vote for an ACCV Chair and Vice Chair and continued with updates from the Division of Injury Compensation (DICP) and the Department of Justice (DOJ). The ACCV also received program updates from the Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease (NIH), the Center for Biologics, Evaluation, and Research (FDA) and the National Vaccine Program Office (NVPO).

03/08/2018 - 03/08/2018

The ACCV conducted its 106th quarterly meeting by teleconference and Adobe Connect on June 15, 2018. The morning began with program updates from the Division of Injury Compensation Programs (DICP) and the Department of Justice (DOJ). The ACCV then received an update from the ACCV Process Workgroup. The ACCV also received program updates from the Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease (NIH), the Center for Biologics, Evaluation, and Research (FDA) and the National Vaccine Program Office (NVPO).

06/15/2018 - 06/15/2018

The ACCV conducted its 107th quarterly meeting in Rockville, MD, and by teleconference and Adobe Connect on September 6, 2018. The morning began with updates from the ACCV Process Workgroup, the Division of Injury Compensation Programs (DICP) and the Department of Justice (DOJ). As part of its mandate, the ACCV also reviewed revisions to Centers for Disease Control and Prevention (CDC) Vaccine Information Statements (VISs) for Meningococcal ACWY and DTap (Diphtheria, Tetanus, and Pertussis) and many comments were provided to CDC staff. Finally, program updates from the Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease, National Institutes of Health (NIH), the Center for Biologics, Evaluation and Research, Food and Drug Administration (FDA) and the National Vaccine Program Office (NVPO) were provided. ,

09/06/2018 - 09/06/2018

## Number of Committee Meetings Listed: 4

	Current FY	Next FY
<b>18a(1). Personnel Pmts to Non-Federal Members</b>	\$17,342.00	\$20,930.00
<b>18a(2). Personnel Pmts to Federal Members</b>	\$0.00	\$0.00

<b>18a(3). Personnel Pmts to Federal Staff</b>	\$294,888.00	\$296,286.00
<b>18a(4). Personnel Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$3,680.00	\$10,921.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$6,905.00	\$6,974.00
<b>18d. Total</b>	\$322,815.00	\$335,111.00
<b>19. Federal Staff Support Years (FTE)</b>	1.50	1.50

**20a. How does the Committee accomplish its purpose?**

The Advisory Commission on Childhood Vaccines (ACCV) accomplishes its purpose by meeting in full session and establishing special topic workgroups. In Fiscal Year 2018, the ACCV continued to meet and have discussions on topics regarding the National Vaccine Injury Compensation Program (VICP). Each meeting included representatives from various Federal government agencies, as well as other stakeholders (i.e. vaccine manufacturer, petitioner's attorney).

**20b. How does the Committee balance its membership?**

The ACCV members consist of three health professionals who are not employees of the Federal Government, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two are pediatricians; three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death; and three attorneys, of whom at least one is an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and one who is an attorney whose specialty includes representation of vaccine manufacturers.

**20c. How frequent and relevant are the Committee Meetings?**

The ACCV meets four times a year to advise the Secretary of HHS on matters related to the implementation of the VICP.

**20d. Why can't the advice or information this committee provides be obtained elsewhere?**

The ACCV members represent the various stakeholders that have an interest in the VICP, and provide scientific, legal and practical advice and recommendations to the Secretary of HHS. This expertise is not available within HHS.

## 20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

## 21. Remarks

No Reports for FY18.

### Designated Federal Officer

Narayan Nair Director, Division of Injury Compensation Programs

Committee Members	Start	End	Occupation	Member Designation
Feemster, Kristen	01/01/2011	12/31/2017	Assistant Professor, UPenn School of Medicine	Special Government Employee (SGE) Member
Gaffney, Kathleen	09/07/2017	12/31/2020	Professor, College of Nursing and Health Science, George Mason University	Special Government Employee (SGE) Member
Howie, John	09/08/2017	12/31/2020	Howie Law, PC	Special Government Employee (SGE) Member
Luthy, Karlen	09/02/2015	12/31/2018	Associate Professor, Brigham young Univeristy	Special Government Employee (SGE) Member
Marshall, Valerie	12/08/2011	12/31/2018	FDA Office of Vaccine Research and Review	Ex Officio Member
McNeil, Michael	12/08/2011	12/31/2018	CDC Immunization Safety Office	Ex Officio Member
Meissner, H. Cody	09/08/2017	12/31/2020	Chief, Pediatric Infectious Disease Service, Tufts Medical Center	Special Government Employee (SGE) Member
Mulach, Barbara	01/01/2002	12/31/2018	National Institute of Allergy and Infectious Disease	Ex Officio Member
Sangiomo, Dino	09/08/2017	12/31/2019	Partner, Veneable LLP	Special Government Employee (SGE) Member
Smith, Jason	01/01/2011	12/31/2016	Pfizer Inc., Assistant General Counsel	Special Government Employee (SGE) Member
Stewart, Alexandra	09/02/2015	12/31/2018	The George Washington University, School of Public Health and Health Services	Special Government Employee (SGE) Member
Tan, Tina	09/08/2017	12/31/2019	Professor of Pediatrics, Northwestern University	Special Government Employee (SGE) Member
Toomey, Martha	09/02/2015	12/31/2018	Parent of Vaccine Injured Child	Special Government Employee (SGE) Member
Wharton, Melinda	12/02/2016	12/31/2019	Acting Director, National Vaccine Program Office	Ex Officio Member
dela Rosa, Luisita	12/01/2011	12/31/2017	Parent of Vaccine Injured Child	Special Government Employee (SGE) Member

**Number of Committee Members Listed: 15**

### Narrative Description

The ACCV provides advice and makes recommendations to the Secretary of HHS regarding the VICP.

### What are the most significant program outcomes associated with this committee?

Checked if Applies

Improvements to health or safety



Trust in government



Major policy changes	<input type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input checked="" type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

### Outcome Comments

NA

### What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

### Cost Savings Comments

The ACCV meetings are sometimes held in the 5600 Fishers Lane Building (a Federal Government facility) conference rooms. They are also sometimes held entirely by conference call which creates a substantial savings by eliminating travel expenses.

### What is the approximate Number of recommendations produced by this committee for the life of the committee?

59

### Number of Recommendations Comments

These recommendations provide advice to the Secretary regarding the VICP.

### What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

42%

### **% of Recommendations Fully Implemented Comments**

These recommendations have been implemented to improve aspects of the VICP. No new recommendations were made in FY 17 but recommendations made in previous years were implemented.

**What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?**

3%

### **% of Recommendations Partially Implemented Comments**

These recommendations have been implemented to improve aspects of the VICP.

**Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?**

Yes ☒ No ☐ Not Applicable ☐

### **Agency Feedback Comments**

The Secretary of HHS acknowledges receipt of the ACCV recommendations, and thanks the ACCV for providing advice and recommendations on the VICP.

**What other actions has the agency taken as a result of the committee's advice or recommendation?**

	Checked if Applies
Reorganized Priorities	<input type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input type="checkbox"/>
Proposed legislation	<input checked="" type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input type="checkbox"/>

### **Action Comments**

NA

**Is the Committee engaged in the review of applications for grants?**

No

### **Grant Review Comments**

NA

**How is access provided to the information for the Committee's documentation?**

Checked if Applies

Contact DFO



Online Agency Web Site



Online Committee Web Site



Online GSA FACA Web Site



Publications



Other



**Access Comments**

N/A